PRISMATIK
DENTALCRAFT, INC.

K 121406

FEB 2 2 2013

005-510 (k) Summary-807.92(c)

This 510 (K) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

A. SUBMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	2212 Dupont Dr., Suite IJK Irvine, CA 92612
Company Phone:	949-225-1269
Company FAX:	949-553-0924
Primary Contact:	Armin Zehtabchi, Senior RA/QA., /Project Manager (949) 225-1234
Secondary Contact:	Marilyn Pourazar Senior Director, RA/QA (949) 225-1269
Date Summary Prepared:	2/20/13

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Inclusive® Tapered Implant System
21 CFR Reference:	21 CFR 872.3640
21 CFR Common Name:	Implant, endosseous, root-form
Classification:	Class II
Product Code:	DZE
Panel:	Dental

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C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name: Inclusive® Mini Implant (K100932), Sulzer's Screw-Vent Dental Implant System (K011028) and KIS-Krauser Implant System (K953235-Transffered to Glidewell Laboratories/Prismatik Dentalcraft, Inc., 2/2011)

D. DEVICE DESCRIPTION

The Inclusive® Tapered Implants are manufactured from biocompatible Titanium alloy. The implant is designed with an internal hex connection and a tapered body to replace one or more missing teeth. The surface is blasted with Hydroxyl Apatite and acid etched to facilitate osseointegration. The Implants are available in the following diameters: 3.7mm, 4.7mm, and 5.2mm, and each diameter is available in the following lengths: 8mm, 10mm, 11.5mm, 13mm, and 16mm. The dental implants are provided sterile (gamma).

E. INDICATIONS FOR USE

Inclusive® Tapered Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

F. SUBSTANTIAL EQUIVALENCE

The Inclusive® Tapered Implant System is substantially equivalent to Prismatik's Inclusive® Mini Implant (K100932), Sulzer's Screw-Vent Dental Implant System (K011028) and the KIS-Krauser Implant System (K953235-Transferred to Glidewell Laboratories/Prismatik Dentalcraft, Inc., 2/2011). These implants are substantially equivalent in intended use, indications for use, material, design and performance.

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Comparison of Predicate Devices

Elements of Comparison	Prismatik's Inclusive® Tapered Implant System	Sulzer's Screw-Vent Dental Implant System (K011028)	KIS-Krauser Implant System (K953235- Transferred to Glidewell Laboratories/Prismatik Dentalcraft, Inc., 2/2011	Prismatik's Inclusive Mini Implant (K100932)
Material	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
Indications	Inclusive® Tapered Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.	Sulzer Dental's implant systems are designed for use in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement. The use of the 4.7mm and 6.0mm implant is recommended when the quantity and density of bone would dictate the use of an implant larger than 4.0mm.	The KIS-Krauser Implant System implants are indicated for single tooth replacements, as intermediate abutments on bridgework, as distal abutments for areas to be restored with fixed bridgework, to support overdentures in the totally edentulous mandible, and as abutments supporting a full arch fixed prosthesis.	Inclusive® Mini Implants are self-tapping threaded titanium screws indicated for long-term application. Inclusive® Mini Implants may also be used for provisional applications. These devices will allow immediate loading and long-term stabilization of dentures and provisional stabilization of dentures while standard implants heal. To be used for immediate loading only in the presence of primary stability and appropriate occlusal.
Design	Threaded root-form implant	Threaded root-form implant	Threaded root-form implant	Threaded root-form implant
Implant Body Geometry	Screw type	Screw type	Screw type	Screw type
Diameters (mm)	3.7, 4.7 and 5.2	3.7, 4.7 and 6.0	4, 5 and 6	2.2, 2.5, 3.0
Lengths (mm)	8, 10, 11.5, 13, and 16	8, 10, 13 and 16	8, 10, 13, 15, 18	10, 13, 15
Driver Connection	Hex	Hex	Hex	Square
Prosthetic Head	Internal	Internal	External	N/A
Sterility	Packaged Sterile	Packaged Sterile	Packaged Sterile	Packaged Sterile

G. PERFORMANCE DATA

The following FDA's Guidance Document "Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments was used for the purpose of Implant to Abutment Compatibility. The Tapered Implant was used for the fatigue testing on the 30° Multi-Unit Abutments and by following the ISO 14801: 2007- Dentistry — Implants —Dynamic fatigue test for endosseous dental implants. All testing conducted met the acceptance criteria and evaluated the worst case scenario. In addition, performance testing data indicated the compatibility, and the safety and the effectiveness of the proposed device which meets the mechanical properties. In addition, to assure the biocompatibility, the following tests were performed, and the reports for the results indicated satisfactory and meeting the acceptance criteria:

1) Irritation (applying ISO 10993-10: 2010 Tests for Irritation and Skin Sensitization).
2) Media (MEM) Elution test to determine the Cytotoxicity (applying ISO 10993-5: 2009 Biological evaluation of medical devices —Part 5: Tests for *in vitro* cytotoxicity
3) Sensitization Tests for Irritation and Skin Sensitization (applying ISO 10993-10: 2010 Tests for Irritation and Skin Sensitization).

The implant packages are sterilized by a gamma sterilization process that conforms to ISO 11137-1: Sterilization of health care products —Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, and ANSI/AAMI/ISO 11137-2: Sterilized of Health Care Products-Radiation-Establishing the sterilized dose.

H. COMPARISON OF TECHNOLOGICAL DIFFERENCES

There are no known technological differences between the Inclusive® Tapered Implant and those of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 22, 2013

Mr. Armin Zehtabchi
Senior Regulatory Affairs / Quality Assurance, Project Manager
Prismatik Dentalcraft, Incorporated
2212 Dupont Drive, Suite IJK
IRVINE CA 92612

Re: K121406
Trade/Device Name: Inclusive Tapered Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: February 11, 2013
Received: February 12, 2013

Dear Mr. Zehtabchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K121406

Device Name: Inclusive Tapered Implant System

Indications for Use:

Inclusive® Tapered Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121406